

Attorney Docket No.: PENN0870US.NP
Inventors: Sweeney et al.
Serial No.: 10/566,796
Filing Date: April 2, 2008
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REMARKS

Claims 1-18 are pending in the instant application. Claims 1-18 have been rejected. Claims 1, 5, 10 and 14 have been amended. Claim 9 has been canceled in light of the amendments to claim 5. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Species Election Requirement

The Examiner made final the species election requirement mailed March 10, 2010. Applicants believe that arguments presented herein overcome the pending art rejection. As Applicants believe the generic claim is in condition for allowance, consideration of claims to additional species which depend from or otherwise require all the limitations of the allowable generic claim is requested.

**II. Rejection of Claims 1-18 under 35 U.S.C. 112, first paragraph
- Written Description**

Claims 1-18 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner suggests that the specification does not provide adequate written description for the phrase "a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk inhibitor."

Applicants respectfully traverse this rejection.

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However, in an earnest effort to advance the prosecution of this case and without acquiescing or agreeing to this rejection, Applicants have amended the claims to delete the phrase "a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk inhibitor." Applicants reserve all rights to pursue claims without amendment as presented herein in this application and/or in any continuation and/or divisional applications of the instant application.

Withdrawal of this rejection is respectfully requested.

**III. Rejection of Claims 1-4 under 35 U.S.C. 112, first paragraph-
Enablement**

Claims 1-4 have been rejected under 35 U.S.C. 112, first paragraph. The Examiner has acknowledged the specification to be enabling for treating skeletal muscle atrophy in a subject comprising administering a Bowman-Birk inhibitor concentrate. However, the Examiner suggests that the specification does not reasonably provide enablement for inhibiting progression of skeletal muscle atrophy in a subject comprising administering a Bowman-Birk inhibitor concentrate. The Examiner suggests that the term inhibit is the same as prevent since they both mean stop from occurring and it is well-accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented/inhibited with current therapies.

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Applicants respectfully traverse this rejection.

Applicants disagree that "prevent" and "inhibit" both mean stop from occurring. "Inhibiting" is by no means an absolute definition that means to "to stop from occurring," While "inhibiting" can mean the ability "to stop from occurring", in the context of pharmacological activity it is well-established that this term encompasses a continuum or spectrum of inhibitory activity ranging from highest to lowest: prevent>treat>ameliorate or alleviate.

At page 4, lines 25-26 of the instant specification, "a method for alleviating symptoms or slowing disease progression" is disclosed. Further, at page 9, line 15, of the instant specification it is taught that "BBIC ameliorates..muscle atrophy." These teachings are clearly enabling for a method of inhibiting progression of skeletal muscle atrophy as claimed.

In an earnest effort to advance the prosecution and without acquiescing or agreeing to this rejection, however, Applicants have amended claim 1 to recite slowing progression of skeletal muscle atrophy in accordance with teachings throughout the specification, for example, at page 13, lines 5-16.

Withdrawal of this rejection is respectfully requested.

IV. Rejection of Claims 1-18 under 35 U.S.C. 112, second paragraph

Claims 1-18 have been rejected under 35 U.S.C. 112, second

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paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that the phrase "a synthetically derived compound which mimics the protease inhibitory activity of Bowman-Birk inhibitor" is vague and indefinite.

As discussed in Section II, *supra*, the claims have been amended to delete this phrase.

Withdrawal of this rejection is therefore respectfully requested.

V. Rejection of Claims 1-17 under 35 U.S.C. 102(a) and Claims 1-18 under 35 U.S.C. 103(a)

Claims 1-17 have been rejected under 35 U.S.C. 102(a) as being anticipated by Morris et al.

Claims 1-18 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. in view of Lynch.

Applicants respectfully traverse these rejections.

MPEP 2132.01 and the case law make clear Applicants' disclosure of their own work within the year before the application filing date cannot be used against them under 35 U.S.C. 102(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

Accordingly, in an earnest effort to advance the prosecution of this case and in accordance with *In re Katz*, 687 F.2d 450, 215

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USPQ 14 (CCPA 1982), Applicants are submitting herewith a Declaration by inventor H. Lee Sweeney stating that co-author Linda Morris of the Morris et al. Biosis Abstract, was "a technician: in Dr. Sweeney's laboratory and performed experiments, in particular isolated muscle mechanics experiments, under his direction. See paragraph 3 of Dr. Sweeney's Declaration. Further stated in Dr. Sweeney's Declaration concerning Linda Morris is that "while her assistance was a tremendous aid to obtaining the data disclosed in this Abstract, she did not contribute to the actual invention claimed in U.S. Application Serial No. 10/566,796." See paragraph 3 of Dr. Sweeney's Declaration.

This Declaration clearly establishes that the Biosis Abstract of Morris et al. was derived from the work of co-inventors H. Lee Sweeney, Carl A. Morris and Ann R. Kennedy (see paragraph 1 of Dr. Sweeney's Declaration) and therefore cannot be used against them under 35 U.S.C. 102(a). See MPEP 2132.01 and *In re Katz* 687 F.2d 450, 215 USPQ 14 (CCPA 1982).

Accordingly, the Morris et al. Biosis Abstract is not a valid reference with respect to the instant claimed invention under 35 U.S.C. 102(a) or 35 U.S.C. 103(a).

The secondary reference of Lynch, cited in the rejection under 35 U.S.C. 103(a), fails to provide the requisite teaching or suggestion with respect to the instant claimed invention to render

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obvious this invention. Lynch et al. is unrelated to BBI.

Withdrawal of these rejections under 35 U.S.C. 102(a) and 35 U.S.C. 103(a) is therefore respectfully requested.

VI. Rejection of Claims 5-8 under 35 U.S.C. 102(b)

Claims 5-8 have been rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al. (U.S. Patent 5,961,980).

It is respectfully pointed out that claim 5 has been amended to include the recitation from nonrejected claim 9 that the improved skeletal muscle function comprises increased muscle strength or increased muscle mass. Claim 9 has been canceled in light of the amendment to claim 5.

Kennedy et al. does not teach the element of improved skeletal muscle function comprising increased muscle strength or increased muscle mass. Nor does it follow by scientific reasoning that BBI, shown by Kennedy et al. to be useful in treatment of genitourinary tract diseases relating to smooth muscle contraction, would increase skeletal muscle strength or muscle strength. Thus, the claims as amended to recite that the improved skeletal muscle function comprises increased muscle strength or increased muscle mass cannot be anticipated by Kennedy et al. See MPEP 2131.

Withdrawal of this rejection is respectfully requested.

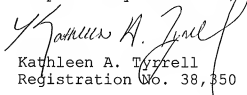
VII. Conclusion

Applicants believe that the foregoing comprises a full and

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complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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